



Sinai Hospital  
Northwest Hospital  
Levindale Hebrew Geriatric Center and Hospital  
Courtland Gardens Nursing & Rehabilitation Center  
**June 30, 2014**

Neil M. Meltzer  
President and Chief Executive Officer

BY FAX & EMAIL

Paul Parker  
Director, Center for Health Care Facilities Planning & Development  
Maryland Health Care Commission  
4160 Patterson Avenue  
Baltimore, Maryland 21215

Re: Proposed Permanent Regulations - State Health Plan for Facilities and Services:  
Specialized Cardiovascular Services, COMAR 10.24.17

Dear Mr. Parker:

I am writing on behalf of LifeBridge Health, Inc., the parent of, among other entities, Sinai Hospital of Baltimore, Northwest Hospital Center and Levindale Hebrew Geriatric Center and Hospital. These comments are being submitted during the public comment period in response to the Proposed Permanent Regulations for the State Health Plan for Facilities and Services: Specialized Health Care Services – Cardiac Surgery and Percutaneous Coronary Intervention Services.

LifeBridge commends the Commission on the clinical, quality and regulatory aspects of its new process for oversight of cardiac services. The Commission has achieved its stated goal to incorporate quality standards and performance measures into the State Health Plan for these services. This focus leads the State toward maintaining its system of high-value programs and ensures that Marylanders will continue to have access to specialized cardiovascular services in appropriate clinical settings. With this accomplishment in mind, we recommend the following changes to the proposed regulations.

Opportunity to Cure / Plan of Correction. We strongly support the new authority of the MHCC to conduct peer and independent review, including focused review and, if necessary, to move toward closure. An essential step in this process is the requirement that programs be given an opportunity to address deficiencies prior to actual closure. We commend the Commission for responding to our earlier recommendation that the language clarify that programs shall be afforded the opportunity to cure defects through a plan of correction. The Commission has, indeed, set out a process by which that plan shall be developed and implemented prior to closure, and we generally support that process. A few suggested changes will confirm the Commission's intent.

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The proposed regulations express this concept very generally, while instead, it needs to refer to the actual plan created after a specific focused review. In instances where the regulations reference “an approved plan of correction,” they should, instead, refer to “the” approved plan of correction. For example, in Section 10.24.17.07.B(2)(d), page 34, the language should read, “The plan of correction developed under Section 10.24.17.07.B(2)(c). . .” In this way, the parties will avoid confusion about whether more than one plan is being referred to. Other instances of this language include, but are not limited to, Section 10.24.17.07C(2)(c) on pages 37-38 and Section 10.24.17.07D(2)(d) on page 44. (On a clerical note, please see Section .07A(5)(A), page 32, which refers to subsections that do not appear in the document.)

On a related matter, Sections 10.24.17.07(6), pages 40-41, and Section 10.24.17.07D(7), pages 48-49, respectively, addressing Physician Resources, should include a parallel opportunity to cure through the approved plan of correction, as set out for other elements of the Plan. This appears to be a drafting issue, where “shall” should replace the discretionary “may” and the process language from the other sections as described above should follow.

Submission of Raw Data. The proposed regulations require hospitals with cardiac surgery programs to participate in the STS-ACSD, a requirement which LifeBridge supports. The regulations then go on to require submission of data, which is inherently duplicative, to the Commission. See Section 10.24.17.07 B(3), pages 34-35, requiring that “each cardiac surgery program shall also cooperate with the data collection requirements deemed necessary” by the Commission. We agree with the Commission that submission of data to the STS achieves the Commission’s goal of obtaining quality scoring in the most efficient, effective and objective manner. We believe, however, that it is redundant, time-consuming and expensive for both programs and the Commission to require submission of this data to the Commission as well. This duplicative process will not enhance the process in any way that will produce objective analysis that will, in turn, lead to additional quality achievements. Perhaps the Commission can consider collaboration with the MCSQI, or consider obtaining compiled STS data from Duke instead of requiring duplicative submission of data from hospitals that the Commission must then interpret.

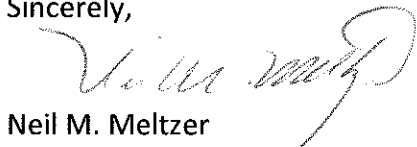
External Review. Earlier versions of the regulations reflect the Clinical Advisory Group’s recommendation of annual external peer review for PCI. The proposed regulations call for semi-annual external review of PCI programs, at the discretion of the Commission. See Sections 10.24.17.07C(4)(c), page 39 and 10.24.17.07(D)(5)(c), page 47. Before a requirement of semi-annual review can be included in regulations, it should be considered by the Clinical Advisory Group, as this level of review is unduly burdensome and expensive to PCI programs and potentially to the Commission itself, without any discernible improvement in quality. This requirement is especially burdensome when coupled with the requirements for specified percentages of PCI cases to be subjected to external review and we ask that both of these requirements be reconsidered by the Clinical Advisory Group before being included in regulation.

Impact Upon Financial Viability. We acknowledge that a cardiac services program – whether a freestanding PCI program or one co-located with a cardiac surgery program – has a financial impact upon its host hospital. The Commission has attempted to embrace the principles of the new reimbursement system along with the hospitals subject to that new system. This requirement is, however, somewhat anachronistic in that the standards do not recognize that most hospitals are on a global budget. For example, in evaluating a relocation, consideration must be given to the potential impact of shifting cases FROM other hospitals, See Section 10.24.17.05C, but under a global budget there could also be negative financial consequences for neighboring hospitals if cases are directed TO them as a result of a relocation. Language on page 18 that talks about the "financial viability of cardiac surgery services" is no longer relevant under the new system. Similar language is found on page 23, in the requirement that new programs show that within three years, revenue from cardiac surgery cases will exceed total expenses if utilization forecasts are achieved. That view of hospital profitability simply does not reflect the global budget environment.

Moreover, the focus on financial viability further contravenes the Commission's appropriate focus on quality. The proposed regulations generally provide protection against proliferation that could result in inefficient use of the scarce resources required to maintain a high quality system of cardiovascular services throughout the State. The standard at Section 10.24.17.06B(3), however, seems to contradict this principle. By allowing an exception to waive volume requirements for addition of an elective PCI program to an existing primary PCI program solely based on permitting the PCI programs to achieve financial viability, the standard ignores the otherwise omnipresent quality-oriented standards that are the hallmark of the Commission's new regulatory oversight structure. This language should be redirected to focus on quality, perhaps limiting it to rural areas where the concern is most prevalent, or to cases in general where closure of the primary component of the program would have a demonstrated negative impact on patient care. Simply waiving the volume requirement – long considered a proxy for quality, or at least an indicator of likely quality levels – not only contravenes the Commission's goal to restructure its regulatory oversight to a quality-based system, but also is inconsistent with the new global reimbursement system.

In conclusion, we commend the Commission once again for its commitment to seek creative solutions to the challenges resulting from changes in the healthcare system and improvements in medical care, and we thank you for the opportunity to comment on the Proposed Permanent Regulations.

Sincerely,



Neil M. Meltzer  
President & Chief Executive Officer